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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Mark Eisenberg. Doc. 7291. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard IVC filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Eisenberg as an expert witness on various issues, including concerns about the safety and efficacy of Bard filters, Bard's obligations to perform safety studies and inform physicians and patients about them, whether the filters were as safe and effective as their predicate devices, and the interpretation of certain clinical studies. Dr. Eisenberg is a board-certified interventional cardiologist. He regularly treats patients with deep vein thromboses and pulmonary emboli, including patients implanted with IVC filters and those who may be candidates for implantations, although he does not implant filters himself. He is also a clinical epidemiologist, having obtained a master's degree from the Harvard School of Public Health. Doc. 7293 at 4-5.[1]

Defendants challenge Dr. Eisenberg's opinions on several grounds. Defendants contend that his opinions about Bard's responsibilities and alleged unethical conduct are not the proper subject of expert testimony, and that he is not qualified to render such opinions. Doc. 7291 at 3-4, 6-11. Defendants make the same arguments as to opinions regarding Bard's knowledge, motives, intent, and state of mind. *Id.* at 11-13. Defendants further argue that factual narratives and "common sense" opinions will not assist the jury. *Id.* at 13-18. Finally, Defendants argue that Dr. Eisenberg cannot speak on behalf of all physicians and patients. *Id.* The Court will address each argument.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Opinions Regarding Ethics and State of Mind.

Plaintiffs agree that Dr. Eisenberg may not opine on Bard's "ethics, motivations, intentions, and state of mind" (Doc. 7810 at 2), but the parties disagree on whether Plaintiffs intend to have him testify on those topics. Plaintiffs assert that his 47-page report contains no opinion that Bard's conduct was unethical, but instead states opinions on "the evidence concerning safety and efficacy of Bard's filters, the information that physicians and patients need for proper informed consent and medical decision-making, and an evaluation of Bard's disclosures of the information it had." Doc. 7810 at 2. Defendants counter that Plaintiffs are attempting to recast Dr. Eisenberg's report and sworn testimony as anything other than ethics opinions, and note that another court has rejected a similar attempt. Doc. 8222 at 2; *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010).

The Court does not find it helpful to cast the issue in terms of ethics vs. non-ethics, but instead will focus on Dr. Eisenberg's specific assertions and the bases for them. He opines that, in light of various "safety signals," Bard had a responsibility to perform large prospective safety studies and randomized controlled clinical trials. Doc. 7293 ¶¶ 30, 34,

197-98, 202, 207, 213. He devotes an entire section of his report to Bard's responsibility to do safety studies. *Id.* ¶¶ 193-210 (§ IV.K). He asserts that Bard did not conduct such studies, but instead "downplayed the documented high rates of adverse events with the Recovery and G2 filters" and had a "corporate policy to not share any of these complication rate analyses with anyone outside the company." *Id*. ¶¶ 85-86, 173. He opines that Bard looked "for ways to avoid being forthright" and spent "time, money and company resources on a media company and PR for 'spin control.'" *Id.* ¶ 95. He claims that Bard performed no studies because it did not want to know the answer – "If you don't want to know the answer, then don't look" – and that Bard "effectively allowed patients to be experimental subjects." *Id.* ¶¶ 35-36.

In short, Dr. Eisenberg expresses strong opinions on what Bard knew, what Bard was obligated to do in light of that knowledge, and how Bard failed to fulfill its obligation and chose instead to mislead physicians. The Court concludes that the cited bases for these opinions either are not relevant, fail to satisfy Rule 702(c), or are outside his area of expertise.

Dr. Eisenberg cites the American Medical Association Code of Medical Ethics and an American College of Radiology practice guideline for informed consent. Doc. 7293 ¶ 24-26. These documents contain ethical and practice guidance for doctors; they say nothing about the legal responsibilities of device manufacturers. Later, Dr. Eisenberg cites an FDA guidance document and a World Health Organization report on pharmacovigilance (*id.* ¶ 42), but he does not purport to be an FDA regulatory expert or an expert in pharmacovigilance. Doc. 7291-2 at 11-12. Dr. Eisenberg also cites an internal Bard Standard Operating Procedure and states: "In my opinion, this Standard Operating Procedure sets a *minimum standard* for when a device failure rate is unacceptable and must be corrected." Doc. 7293 ¶ 49 (emphasis added). But his only explanation for the source of this "minimum standard" is what a "reasonably prudent physician" would expect of a medical device manufacturer. *Id.* What a reasonably prudent physician would expect may be relevant in a medical malpractice case where the

medical standard of care is at issue, but Plaintiffs cite no authority to show that it sets the legal standard for medical device manufacturers under the state tort laws applicable in this MDL proceeding. Finally, Dr. Eisenberg states that the standards underlying his opinions "form the foundation of our medical system" (*id.* ¶ 42), but citing such imprecise and general standards does not satisfy Rule 702(c).

Dr. Eisenberg's deposition makes clear that his opinions are based not on any "scientific, technical, or otherwise specialized knowledge" as required by Rule 702(a), but on his own personal views about proper corporate behavior. He admitted that it was fair to describe his opinions as "based on what [he] believe[s] a responsible, ethical and moral device manufacturer" would have done. Doc. 7291-2 at 28 (Dep. Tr. 89:21-15). Personal views on proper corporate behavior are not appropriate expert opinions. *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007); *see also Trasylol*, 2010 WL 1489793, at *9 (finding Dr. Eisenberg's opinions on Bard's responsibilities inadmissible under Rule 702 because they were based on speculation and the doctor's subjective beliefs rather than any objective standard or specialized knowledge); *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 542-43 (S.D.N.Y. 2004) ("The opinions of plaintiffs' witnesses, however distinguished these individuals may be as physicians and scientists, concerning the ethical obligations of pharmaceutical companies and whether the defendants' conduct was ethical are inadmissible[.]"); Doc. 9433 at 17 (holding that no expert, on either side, will be permitted to opine on intent or ethics).

Dr. Eisenberg also expresses opinions about what Bard knew based on various internal documents, how Bard tracked adverse event reports, and what Bard failed to take into account in designing its filters. *See, e.g.*, Doc. 7293 ¶¶ 31, 69, 75, 82-85, 97, 106, 112, 115. But Dr. Eisenberg is not an expert on corporate communications, behavior, or regulation, and he admits that he has no "specific training looking at company documents and identifying what the company knows or doesn't know[.]" Doc. 7291-3 at 4-5 (Dep. Tr. 59:5-60:67). Nor has he conducted any study of Bard internal operations, information

gathering, or design processes. To the extent Dr. Eisenberg "offers opinions on Bard's intent, state of mind, or motivations, this testimony is outside the bounds of appropriate expert testimony." *Tillman v. C. R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015).

Plaintiffs assert that Dr. Eisenberg should be allowed to testify, within scope of his specialized knowledge, regarding the information physicians must possess if they are to obtain informed consent from their patients. Doc. 7810 at 8. But even if such physician information is relevant for the jury to decide whether Bard is liable for a failure to warn, it is not relevant in the way Dr. Eisenberg intends to use it – to establish Bard's legal obligations. It cannot be used, as Plaintiffs propose, to establish "what steps must be taken" by a medical device manufacturer "in response to safety signals in order to improve patient safety." *Id.* The Court will instruct the jury on how to determine Defendants' duty in this case, and testimony from FDA regulatory experts may be relevant to that determination. But Dr. Eisenberg's personal opinions cannot supply the standard.

In summary, Dr. Eisenberg will not be permitted to render opinions about what Bard did or should have done; to testify about Bard's corporate knowledge, internal conduct, or intent; or to testify about what steps must be taken by a medical device manufacturer in response to safety signals or to improve patient safety. He is an interventional cardiologist with training in clinical epidemiology; Plaintiffs have not shown that he is qualified to testify on these subjects or that his proposed testimony is based on reliable principles and methods. Fed. R. Evid. 702.

B. Narrative Testimony.

Dr. Eisenberg's report includes a discussion of the history of Bard filters and internal company documents. *See, e.g.*, Doc. 7293 ¶¶ 56-72. Defendants contend that these factual narratives are not helpful to the jury or appropriate subjects of expert testimony, and serve only to circumvent the proper presentation of evidence at trial. Doc. 7291 at 13-16. The Court previously has explained that although experts in this

case may explain the factual basis for their opinions, they will not be permitted to gratuitously comment on factual evidence or engage in lengthy factual narratives not necessary to the jury's understanding of their opinions. Doc. 9434 at 4. At trial, the Court will seek to strike the proper balance between allowing experts to reasonably explain their opinions in a manner helpful to the jury, and avoiding unnecessary factual recitation or argument. *See id.* The Court cannot draw lines now.

C. "Common Sense" Opinions.

Defendants cite portions of Dr. Eisenberg's deposition where he testified that the significance of some Bard internal documents would be readily apparent to the jury, or where he expressed views based on common sense. Doc. 7291 at 18. To the extent Plaintiffs intend to have Dr. Eisenberg review internal Bard documents and simply confirm what he believes they would show to any reasonable juror, or state what he believes they show as a matter of common sense, such testimony will not be permitted. It is not based on expertise and would not assist the jury as required by Rule 702(a).

D. Opinions About Other Physicians.

Defendants ask the Court to exclude Dr. Eisenberg's opinions about the reasonable expectations all physicians have of medical device companies like Bard. Doc. 7291 at 16-17. Plaintiffs counter that Dr. Eisenberg opines about informed consent standards, not other physicians' states of mind. Doc. 7810 at 18. Plaintiffs assert that "[w]hile Bard focuses on whether Dr. Eisenberg can testify to how other physicians would react to complication rates, the principle focus of [his] testimony is what physician's need to perform their duties[.]" *Id.* at 19.

As noted above, Dr. Eisenberg will not be allowed to use physician expectations to establish Bard's legal obligations.

Furthermore, throughout his report Dr. Eisenberg offers opinions about what other physicians would think and do with certain information about Bard filters. He opines that "physicians who use IVC filters would agree that Bard's standard [operating procedure] is at best a minimum standard" (Doc. 7293 ¶ 49), that physicians "who became aware of

the adverse event rates that Bard was observing would likely have stopped using these devices immediately" (¶ 86), and that the adverse event rates "would have persuaded most physicians from using [the Recovery] device" (¶ 137). But Dr. Eisenberg has never implanted or removed an IVC filter and does not claim to be an expert on IVC filters. Doc. 7291-2 at 5-6. He has done no research on IVC filters prior to his retention in this litigation. *Id.* at 5. He lacks the specialized knowledge and experience needed to opine about how IVC-filter physicians would respond to facts at issue in this case, and will not be permitted to give such opinions. Fed. R. Evid. 702.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Mark Eisenberg (Doc. 7291) is **granted** to the extent set forth in this order.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge